

PATENT**REMARKS**

Claims 1 and 3-23 are currently pending in this application. Claim 21 has been amended. New claims 22 and 23 have been added. No new matter has been added by these amendments or additions. Applicants have carefully reviewed the Office Action and respectfully request reconsideration of the claims in view of the remarks presented below.

Claim Rejections Under 35 U.S.C. §102

Claims 1-3, 5, 7 10-16 and 21 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,381,493 (Stradler et al.).

Independent claims 1 and 21 relate to methods and systems for detecting ischemia based on T-wave energy values and T-wave maximum slopes. For example, claim 1 recites detecting a plurality of individual T-waves within cardiac signals; determining an energy value and a maximum slope for each of the plurality of individual T-waves; and detecting cardiac ischemia based on the energy values and the maximum slopes.

It appears from the Office Action, and particularly the Response to Arguments section, that the rejections of Applicants' claims are based on an interpretation that some of the ST segment features disclosed in Stradler et al. correspond to T-wave features recited in Applicants' claims. The definition of T-wave in U.S. Patent No. 5,148,812 (Verrier et al.) is cited in paragraph 3 of the Office Action to support this interpretation. However, that Verrier et al. chose to define a T-wave to include both the ST segment and the T wave, does not *ipso facto* mean that such definition applies to Stradler et al. In fact, Stradler et al. states that the T-wave is at the termination of the ST segment. See column 2, lines 9-10. Therefore, as a threshold matter, Applicants submit that particular relevant T-wave features, such as T-wave slopes, have been improperly read into Stradler et al.

Regarding the claimed "maximum slopes," in the Response to Arguments section of the Office Action, various portions of Stradler et al. are cited as disclosing the use of

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a maximum slope. Applicants have reviewed the cited portions of Stradler et al. and disagree with their characterization. Applicants acknowledge that Stradler et al. does disclose an ST segment slope parameter that is calculated as the absolute value difference between first and second ST segment data point values. See column 20, line 61-63 and column 21, lines 64-67. Stradler et al., however, does not identify any calculated ST segment slope as a maximum ST segment slope. Furthermore, in view of the proceeding paragraph, even if a maximum ST segment slope were disclosed in Stradler et al., such a slope would not be a maximum T-wave slope.

In view of the foregoing, Applicants submits that Stradler et al. fails to disclose a maximum T-wave slope. Accordingly, Applicants request reconsideration of the §102 rejections of independent claims 1 and 21 and their respective dependent claims.

Claim 17 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,148,812 (Verrier et al.)

Claim 17 recites a T-wave detection subsystem operative to detect a plurality of individual T-waves in a cardiac signal; a T-wave energy integration subsystem operative to detect a total energy for each of a plurality of the individual T-waves; and a cardiac ischemia detection subsystem operative to detect cardiac ischemia based on the total energy of one of the individual T-waves, an average of the total energies of a plurality of the other T-waves and a threshold value.

Verrier et al. discloses a system for monitoring alternations in T-waves. To this end, a T-wave is partitioned into "B" time divisions (plural), where "B" may include either 1) a single digital sample or 2) a plurality of samples. See column 6, lines 42-45. Alternatives 1) and 2) are illustrated below in figures A and B respectively.

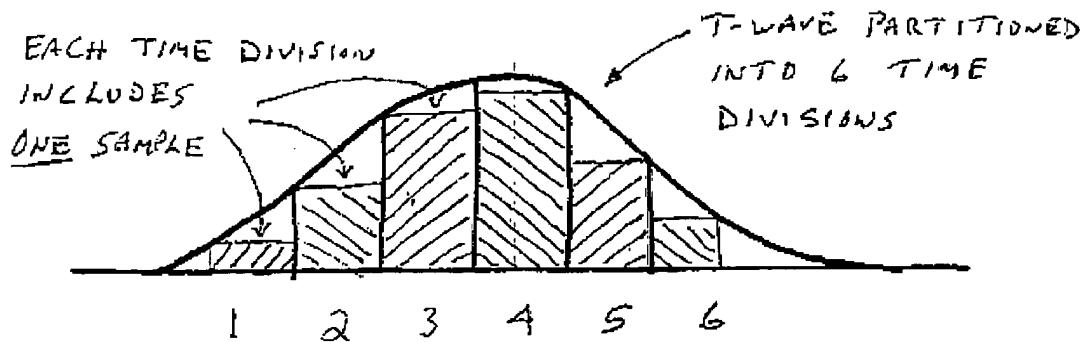
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FIG. A

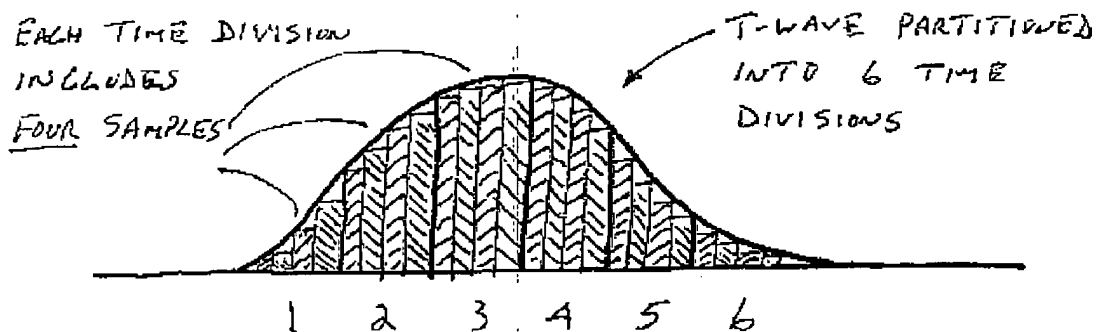


FIG. B

The area between the ECG (T-wave) and the isoelectric line is computed for each time division (not entire T-wave) by summing the areas of all samples in the time division. See column 6, lines 45-48. This partitioning/sampling/summing process is repeated for "N" successive T-waves to produce a sequence, or time series, of "N" summations for each particular time division that are further processed in order to estimate the beat-to-beat alternations associated with the particular time division (not entire T-wave). See column 6, lines 48-59 and column 7, lines 14-16. Thus, any alternation measurement is done on a time-division-by-time-division basis.

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In paragraph 5 of the Response to Arguments section of the Office Action, it is maintained that Verrier et al. "clearly states that the energy of the entire T-wave is computed when "B" is a single digital sample." Applicants' interpretation of this statement is illustrated below:

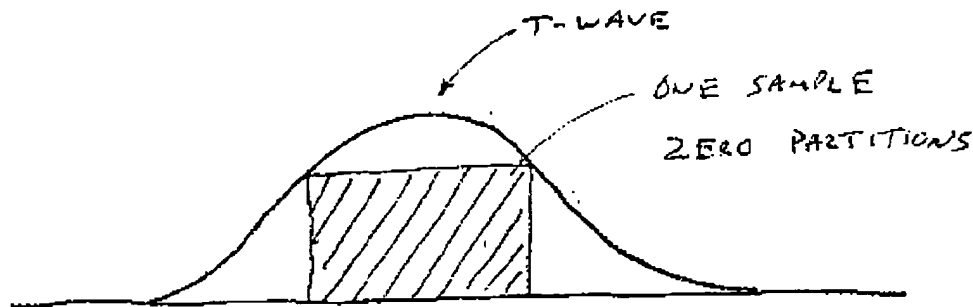


FIG. C

If Applicants' interpretation of the cited statement is correct, Applicants submit that Verrier et al. does not support this interpretation. It is noted that column 6, line 42 of Verrier et al., cited in the Office Action, states that "B" may include a single digital sample, not that "B" is a single digital sample. The significant distinction between the two is evident when comparing figure A (time division may include a single digital sample) and figure C (time division is a single digital sample).

In view of the foregoing, Applicants submit that Verrier et al. fails to disclose the determination of the total energy of a T-wave. Furthermore, Verrier et al. fails to disclose a subsystem operative to detect cardiac ischemia based on the total energy of one of the individual T-waves, an average of the total energies of a plurality of the other T-waves and a threshold value. Accordingly, Applicants request reconsideration of the §102 rejections of independent claim 17 and its dependent claims.

PATENT**Claim Rejections Under 35 U.S.C. §103**

Claims 6 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Stradler et al. Claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over Stradler et al. in view of U.S. Patent Publication 2002/015807 (Goldin). Claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Stradler et al. in view of Verrier et al. Claims 18-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Verrier et al. in view of Stradler et al.

In view of the foregoing analysis of independent claims 1 and 17 in view of Stradler et al. and Verrier et al. Applicants believe that the rejections under §103 are rendered moot as each of dependent claims 4, 6, 8, 9 and 18-20 depend from allowable independent claims.

New Claims 22-23

New independent claim 22 recites a method including calculating a total energy for each of a plurality of individual T-waves and detecting cardiac ischemia based on the total energy of one of the individual T-waves, an average of the total energies of a plurality of the other T-waves and a threshold value. New dependent claim 23 recites that products of the energy values and the maximum slopes are used to detect cardiac ischemia. Neither Stradler et al. nor Verrier et al. disclose the features of these claims.

PATENTCONCLUSION

Applicants have made an earnest and bona fide effort to clarify the issues before the Examiner and to place this case in condition for allowance. Therefore, allowance of Applicants' claims 1 and 3-23 is believed to be in order.

Respectfully submitted,

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Date


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